

amended claims is merely a matter of preference in describing the claimed invention, and is not meant as a reflection of changes deemed necessary for patentability purposes.

Respectfully submitted,

*Marilyn Amick*

Date: June 15, 2001

Marilyn L. Amick, Reg. No. 30,444  
Roche Diagnostics Corporation  
9115 Hague Road, Bldg. D  
P.O. Box 50457  
Indianapolis, IN 46250-0457  
Telephone No.: (317) 521-7561  
Facsimile No.: (317) 521-2883

*G:\CORE\PLD\IDs\00100-00199\00115us\Preliminary Amendment.doc*



RECEIVED

JUN 26 2001

RDID 00115 US

TECH CENTER 1600/2900

- sub  
BI
- A
44. A method for the detection of a homogeneous or heterogeneous analyte population in a sample comprising the steps of:
- (a) providing a solid phase comprising a non-porous support and at least two spatially separate test areas, each test area comprising a receptor capable of binding specifically with said analyte, said receptors being bound directly or indirectly to the non-porous support and, in the case of a heterogeneous analyte, binding to a partial population of the analyte, and in the case of a homogeneous analyte, binding to different epitopes of the analyte,
  - (b) contacting the sample with the solid phase and with a detection reagent comprising a receptor capable of binding with the analyte and bound or capable of being bound to a signal generating group, and
  - (c) determining the presence or amount of the signal generating group bound to the test areas as a measure of the analyte in said sample.
45. The method of claim 44 wherein the analyte is selected from the group consisting of a homogeneous antigen or antibody population, a heterogeneous antibody population, an antigen mixture and a mixture of antigens and antibodies.
46. The method of claim 44 wherein each test area has a diameter of 0.01 to 1 mm.
47. The method of claim 44 wherein the solid phase further comprises a control area.

48. The method of claim 44 wherein said detection reagent is a universal detection reagent comprising labelled latex particles.
49. A solid phase for the detection of a homogeneous or heterogeneous analyte population in a sample comprising a non-porous support and at least two spatially separate test areas, each test area comprising a receptor capable of binding specifically to the analyte, said receptors being bound directly or indirectly to the non-porous support and, in the case of a heterogeneous analyte, binding to a partial population of the analyte, and in the case of a homogeneous analyte, binding to different epitopes of the analyte.
50. The solid phase of claim 49 wherein each test area has a diameter of 0.01 to 1 mm.
51. ~~A test kit for the detection of an analyte in a sample comprising the solid phase of claim 49 and a detection reagent comprising a receptor capable of binding with the analyte and bound or capable of being bound to a signal generating group.~~
52. The test kit of claim 51 wherein said detection reagent is a universal detection reagent comprising labelled latex particles.

53. A method for the simultaneous determination of an antigen and an antibody specifically directed against said antigen in a sample comprising the steps of:
- (a) providing a solid phase comprising a first test area and a second test area, said first test area comprising an immobilized receptor capable of binding to said antigen and said second test area comprising an immobilized receptor capable of binding to said antibody, said test areas being spatially separated and said receptors being bound directly or indirectly to the solid phase,
  - (b) contacting the sample with the solid phase and with a detection reagent comprising a receptor capable of binding with said antigen and bound or capable of being bound to a signal generating group, and
  - (c) detecting the presence or amount of the analyte by measuring the signal generating group bound to the test areas.
54. The method of claim 53 wherein the immobilized receptor comprising said first test area is specific for an epitope of said antigen.
55. The method of claim 53 wherein said solid phase further comprises an additional test area comprising an immobilized receptor capable of binding to a subtype of said antigen.
56. The method of claim 53 wherein the antibody is selected from the group consisting of HIV I antibodies, HIV II antibodies, HBV antibodies and HCV antibodies.
57. The method of claim 53 wherein the immobilized receptor comprising said second test area is an antigen specific for said antibody.

58. The method of ~~claim~~ 53 wherein said antigen is selected from the group consisting of HIV I antigens, HIV II antigens, HBV antigens and HCV antigens.
59. The method of claim 53 wherein said antigen is HIV p24 and said antibody is a p24 antibody.
60. The method of claim 53 wherein said solid phase is non-porous.
61. The method of claim 53 wherein said detection reagent comprises a labelled antibody specific for the antigen.
62. The method of claim 53 wherein said signal generating group is selected from the group consisting of fluorescent groups, chemiluminescent groups, radioactive labels, enzyme labels, coloured labels and sol particles.
63. The method of claim 53 wherein said detection reagent is a universal detection reagent comprising labelled latex particles.
- ✓ 64. A solid phase for the simultaneous determination of an antigen and an antibody directed specifically against said antigen in a sample comprising a first test area and a second test area, said first test area comprising an immobilized receptor capable of binding to said antigen and said second test area comprising an immobilized receptor capable of binding to said antibody.
65. The solid phase of claim 64 wherein said solid phase further comprises a non-porous support.
66. The solid phase of claim 64 wherein said solid phase is comprised of polystyrene.

67. The solid phase of claim 64 wherein each test area has a diameter of 0.01 to 1 mm.
68. A test kit for the simultaneous determination of an antigen and of an antibody directed specifically against said antigen comprising the solid phase of claim 64 and a labelled detection reagent.
69. The test kit of claim 68 wherein said detection reagent is a universal detection reagent comprising labelled latex particles.
-